UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDE AND TOXIC SUBSTANCES

MEMORANDUM

Date: February 17, 2009

SUBJECT: **Phosmet:** Revision To The Occupational Postapplication Exposure and Risk Calculations for Phosmet; D296595; Case #838564.

PC Code: 059201
Decision No.: 396111
Petition No.: NA
Risk Assessment Type: Single Chemical
T**XR No.:** NA
MRID No.: 45138201, 44811801, 44673301, 47262502, 47083001, 47262501, 44795810, 40122201, 40425301, 42595800.

DP Barcode: D296595
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FROM: Matthew Lloyd
Linda Taylor
Risk Assessment Branch 7
Health Effects Division (7509P)

THROUGH: Michael Metzger
Risk Assessment Branch 7
Health Effects Division (7509P)

TO: Veronique LaCapra, Chemical Review Manager
Special Review and Reregistration Division (7508P)

This memo updates the occupational postapplication risk calculations already examined in past HED documents [D355152, D333957, D262366, D268141, D277160] using recently updated hazard information for phosmet.

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1. Occupational Postapplication Exposure

1.1. Occupational Postapplication Exposures and Risks

The Agency uses the term "postapplication" to describe exposures to individuals that occur as a result of working in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). The Agency believes that there are distinct job functions or tasks related to the kinds of activities that occur in previously treated areas such as harvesting vegetables in a treated field. Job requirements (e.g., the kinds of jobs to cultivate a crop), the nature of the crop or target that was treated, and how chemical residues degrade in the environment can cause exposure levels to differ over time. Each factor has been considered in this assessment.

1.1.1. Hazard Information

Since the 2001 IRED, two new toxicological studies pertinent to the postapplication exposure assessment were submitted to the Agency for review. These include:

- a new 21-day dermal toxicity study (MRID 47262502) in rats, and
- an *in vitro* comparative dermal penetration study (MRID 47262501) in rat and human skin.

OPP does not currently have a final policy describing the use of *in vitro* dermal absorption data for determining risks from human dermal exposure; however, the data considered are useful for this purpose. In the absence of a more fully developed policy, HED will take a protective approach when using the phosmet *in vitro* dermal data (MRID 47262501; TXR# 0053048) to inform the postapplication worker risk assessment for the chemical. Thus, HED selected the 2-sided lower 95% confidence interval of the ratio of the rat mean 24-hour cumulative absorption to the human mean 24-hour cumulative absorption (4.5-fold factor). This value is chosen because it is both consistent with HED's current approach of using 24-hour cumulative absorption in estimating dermal absorption values, and it is a protective assumption considering the median ratio of 8.21 and the variability seen in the data (ToxSacMeetingNotes, dated February 21, 2008; Sielken & Associates Consulting, Inc. letters dated April 24 and 25, 2008 to Gowan). This ratio can be used to modify risk assessment points of departure for worker postapplication risk assessments to account for the difference in permeability between human skin and rat skin.

HED has deemed the new 21-day dermal toxicity study (MRID 47262502; TXR# 0053048 and TXR# 0054871) unacceptable for use in risk assessment based on the lack of consistency and reproducibility of the cholinesterase activity measurements and the lack of a clear rationale for the reanalysis that took place (data submissions of February 13, 2008, March 23, 2008, and May 5, 2000; conference call on January 30, 2008; and meetings on April 9, 2008 and May 8, 2008). The registrant (Gowan letter dated December 10, 2007) provided new information regarding the MPI dermal toxicity study (MRID 44795801) in support of their decision to perform another dermal study. The MPI study was used in the previous risk assessment. Gowan indicated, among other things, that the MPI study used a non-validated cholinesterase assay. Although the method used was not cross-validated for rat tissues, based on discussions with ORD, HED considers the brain data to be of sufficient quality for risk assessment. There is low confidence in the RBC data from this study, which stems from the spectrophotometric assay used to measure cholinesterase levels. The use of a spectrophotometric assay often creates difficulties with the analysis of rat RBC cholinesterase, causing considerable variability. Rat RBC samples present with a high background (because of the hemoglobin interference) and low activity (about 10 times lower than human RBCs), create considerable inaccuracy in the assay. Conversely, rat brain cholinesterase measurements do not have these problems; consequently, those data are often less variable and more accurate. Furthermore, confidence in the RBC data is low due, in part, to the fact that in this study the brain appeared to be the most sensitive compartment for cholinesterase inhibition. This is in contrast to the overall phosmet database, which indicates that the RBC is the most sensitive compartment for this compound. Therefore, HED concludes that only the brain data from the MPI study are of sufficient quality for risk assessment.

New dermal endpoints and points of departure were selected for the short- and intermediate-term dermal exposure scenarios using the subchronic oral neurotoxicity (SCN) study in rats (MRID 44811801) as the primary study, supported by the MPI 21-day dermal study in rats (MRID 44795801) as co-critical (ToxSac memo; meeting date January 22, 2009). A $BMDL_{10}$ of 1 mg/kg/day (3 week assessment) for RBC cholinesterase from the SCN study will be used for the point of departure (PoD). Although the SCN study is an oral study and not route specific, there is high confidence in the cholinesterase data from this study with less confidence in the 21-day dermal MPI study for the reasons described in the January 22nd, 2009 ToxSac meeting memo.

Overall, the quality of the SCN cholinesterase data outweighed the uncertainties associated with route-to-route extrapolation. Thus, ToxSAC concluded that using the more sensitive RBC $BMDL_{10}$ data from the oral SCN study, instead of the brain cholinesterase data from the 21-day dermal study, is warranted and would result in a health protective PoD for these risk assessments.

In recent years, OPP has increased its understanding and implementation of benchmark dose (BMD) techniques. BMD methods provide a more robust approach for developing points of departure (PoD) for risk extrapolation, for evaluating relative potency, and evaluating life-stage sensitivity. A Bench Mark Dose (BMD) analysis of the red blood cell (RBC) cholinesterase data from the subchronic neurotoxicity study 3-week assessment provides the most consistent and defensible point of departure (PoD) of 1.0 mg/kg/day ($BMDL_{10}$) for both the short- and intermediate-term dermal assessments. A BMD analysis of the brain cholinesterase data from the MPI dermal study provides a $BMDL_{10}$ of 9.97 mg/kg/day, which is consistent with that found for the SCN RBC data (10% dermal absorption in the rat).

To account for differences in permeability between rat and human skin, the data from the *in vitro* dermal penetration study (MRID 47262501) and the *in vivo* dermal absorption study (MRID 40122201) were applied to the point of departure (PoD) to obtain the human equivalent dermal dose for the short- and intermediate-term dermal risk assessments. The *in vitro* dermal penetration study provides a comparison of permeability between rat and human skin (*in vitro* correction factor). The *in vivo* dermal absorption study shows a 10% dermal absorption factor for the rat. The resulting Human Equivalent Dose for both the short- and intermediate-term dermal assessments is 45 mg/kg/day.

Table 1 – Summary of Hazard Information for Assessing Phosmet Occupational Postapplication Risks

Exposure Scenario	PoD Dose (mg/kg/day)	Endpoint	Study	Dermal Absorption Factor	*In Vitro* Correction Factor	Human Equivalent Dose Used to Quantify Risk (mg/kg/day)
Short- and Intermediate Term Dermal	Oral $BMDL_{10}$ = 1.0	cholinesterase inhibition (3-week RBC)	subchronic neurotoxicity/ rat (MRID 44811801) co-critical MPI 21-day dermal/rat (MRID 44795801)	10%	4.5	45

1.1.2. Occupational Postapplication Exposure Scenarios and Calculation Methods

<u>Exposure Scenarios</u>

The current postapplication occupational exposure assessment is conducted for the nine crops specified in the *Reregistration Decisions on Nine Phosmet "Time Limited" Uses*, dated January 18, 2007. The calculations for postapplication exposure in this document focus on dermal exposures alone because inhalation exposures are thought to be a negligible contribution to postapplication exposure. Applications are typically around two times per year, although phosmet can be used more frequently.

- The Agency uses a concept known as the transfer coefficient to numerically represent the postapplication exposures one would receive (i.e., generally presented as cm^2/hour). These transfer coefficients are listed in Policy 3.1 Science Advisory Council for *Exposure Policy Regarding Agricultural Transfer Coefficients*. In this policy, transfer coefficients were selected to represent the activities associated with 18 distinct crop/agronomic groupings based on different types of vegetables, trees, berries, vine/trellis crops, turf, field crops, and bunch/bundle crops (e.g., tobacco). The transfer coefficients for highbush blueberries were taken from a study submitted by the ARTF (ARF-020, MRID 451382-01) on blackberries.

The relevant crop groups associated with the nine "time-limited" uses of phosmet include:

- Tree/fruit, deciduous (e.g., apples, pears, peaches, nectarines, plums, prunes, apricots);
- Vine/trellis (e.g., grapes)
- Vine/trellis (highbush blueberries)

Within each agronomic group, a variety of cultural practices are required to maintain the included crops. These practices are varied and typically involve light contact with immature plants and heavy contact with more mature plants.

For phosmet, the Agency has completed short- and intermediate-term postapplication assessments because of concerns over extended periods of exposure for a segment of the user population. The Agency believes that phosmet exposures can occur over a single day or up to several weeks at a time for postapplication workers, even though many crops are likely treated only a couple of times per season. This is supported by the length of time residues take to decline in the phosmet dislodgeable foliar residue studies used in past HED risk assessment documents (D262365) and the concept that several areas within a work environment may be treated at different times. For example, parts of agricultural fields in a localized area might be treated over several weeks because of an infestation with a concurrent need for hand labor activities. Therefore, individuals working in those fields might be exposed from contact with treated foliage over an extended period of time that could be categorized as an intermediate-term exposure as they work on different sections of the localized field areas.

Calculation Methods

Postapplication exposures are calculated by considering transferable residue levels in areas where people work and the kinds of jobs or tasks that are required to produce agricultural commodities. These factors are represented by dislodgeable foliar residue (DFR) concentrations and by activity-based transfer coefficients. Exposures are calculated by multiplying these factors by a time component (i.e., an 8 hour work day assumed for seasonal reentry work). Exposures are then normalized by body weight and adjusted for dermal absorption (if necessary) to calculate absorbed doses. Risk estimates were then calculated. Postapplication risks diminish over time because phosmet residues dissipate in the environment.

Estimation of Residue Levels Using Dissipation Kinetics

The first step in the postapplication risk assessment was to complete an analysis of the available DFR data. Best fit DFR levels were calculated based on empirical data using the equation D2-16 from Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines. Half-lives were calculated using the algorithm ($T_{1/2}$ = -Ln 2/slope). The results of those statistical analyses were used to calculate best fit concentrations over time using the following pseudo-first order equation:

$$C_{envir(t)} = C_{envir(0)} e^{(PAI_{(t)} * M)}$$

Where:

$C_{envir(t)}$ = dislodgeable foliar residue ($\mu g/cm^2$) that represents the amount of residue on the surface of a contacted leaf surface that is available for dermal exposure at time (t);

$C_{envir(0)}$ = same as above at time (0);

e =natural logarithms base function;

$PAI_{(t)}$ = postapplication interval or dissipation time (e.g., days after treatment or DAT); and

M = slope of line generated during linear regression of data [ln(C_{envir}) versus PAI].

The data were not corrected for recovery in any calculation by the Agency and it appears that the data also were not corrected by the investigators (i.e., overall field recoveries are around 90%). The same datapoints were used by the Agency in the development of this risk assessment as were used in various risk assessments by the Gowan Corporation in previous submission to the Agency. Analysis of the data can be summarized by the following:

Table 2 – "Best Fit" Dissipation Kinetics Data for Phosmet Postapplication Risk Calculations					
Crop	**Application Rate (lb ai/A)**	**Correlation Coefficient**	**Slope**	**C_0 (µg/cm^2)**	**Half-Life (days)**
Pears	5	0.97905	-0.06621	5.04	10.5
Grapes	1	0.94075	-0.06810	1.70	10.2

Note: *This analysis is based on cumulative residues of phosmet and phosmet oxon.*

In cases where no chemical-specific residue dissipation data are available, the Agency typically uses a generic dissipation model to complete risk calculations. In this case, the Agency has determined that it is more appropriate; however, to extrapolate using phosmet-specific dissipation data in the risk assessment for other currently labelled crops than it is to use the generic dissipation model. This approach is consistent with current Agency policies for generating transferable/dislodgeable residue data. The existing residue data were extrapolated to the currently labelled crops as follows:

- **Pear Data:** These data have been used to complete all occupational assessments that were based on exposures worker reentry activities around tree fruit crops. This extrapolation was completed because of similarities in the application method, the crop canopy, and application rates (i.e., between the study and current labels). These data were extrapolated to various application rates including 4.0 lb ai/acre for pears and apples, 3.0 lbs ai/acre for peaches, nectarines, plums, and apricots, and 2.0 lb ai/acre for apples in the northeast (tank mixed with methomyl [lannate]). Therefore, four different calculations were completed for these postapplication assessments to account for differences between crops due to application rates in order to provide for a more informed risk management decision.

- **Grape Data:** These data have been used to complete the remaining occupational assessments (i.e., postapplication scenarios for highbush blueberries and grapes). This extrapolation was completed because of similarities in the application method, the crop canopy, and application rates (i.e., between the study and current labels). These data were extrapolated to various application rates including 1.5 lbs ai/acre for grapes (to reflect the most recent proposed label rates). No extrapolation was necessary for highbush blueberries because the study was conducted at 1 lb ai/acre and the current label rate is 1 lb ai/A. These calculations for the different label rates were completed for these postapplication activities to account for differences between crops due to application rates in order to provide for a more informed risk management decision.

Daily Exposure: The next step in the risk assessment process was to calculate dermal exposure values on each postapplication day after application using the following equation (see equation D2-20 from *Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines.*

$$\mathbf{DE_{(t)}\ (mg/day) = (DFR_{(t)}\ (\mu g/cm^2)\ x\ TC\ (cm^2/hr)\ x\ Hr/Day)/1000\ (\mu g/mg)}$$

Where:

DE(t)	=	Daily exposure or amount deposited on the surface of the skin at time (t) attributable for activity in a previously treated area, also referred to as potential dose (mg ai/day);
DFR(t)	=	Dislodgeable foliar residue at time (t) ($\mu g/cm^2$);
TC	=	Transfer Coefficient (cm^2/hour); and
Hr/day	=	Exposure duration meant to represent a workday (8 hours).

Margins of Exposure: Finally, the calculations of daily dermal dose received by postapplication workers were then compared to the appropriate PoD (e.g., NOAEL or $BMDL_{10}$) to assess the total risk to postapplication workers for dermal exposure. All risk estimate (MOE) values were calculated for dermal exposure levels using the formula below:

$$\boxed{MOEroute = \frac{PoDroute\left(mg/kg/day\right)}{Average\ Daily\ Dose\left(mg/kg/day\right)}}$$

Where:

MOE	= Margin of exposure, value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless);
ADD	= (Average Daily Dose) or the amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
PoD	= Dose level in a toxicity study, where no observed adverse effects occurred (e.g., NOAEL or $BMDL_{10}$) in the study (mg/kg/day).

A body weight of 70 kg was used to estimate occupational exposures for the postapplication assessment since the relevant toxicological points of departure are not gender specific. The Agency's level of concern (LOC) for phosmet postapplication risk assessment is 100 (i.e, a margin of exposure less than 100 is considered a risk of concern). The LOC is based on a factor of 100 to account for inter-species extrapolation to humans from the animal test species (10X) and to account for the intra-species sensitivity (10X).

1.1.3. Data Used for Occupational Postapplication Exposure Scenarios

Chemical-Specific Data: The postapplication risk assessment for phosmet has been developed using chemical-specific dislodgeable foliar residue data on pears and grapes. In the previous assessments for phosmet, these data were used to calculate risk estimates for the risk manager to set Restricted Entry Intervals (REIs) for occupational exposures.

In order to present a transparent postapplication exposure assessment, it is necessary to present the data upon which it is based. The studies used to determine the dislodgeable foliar residue levels and human exposure levels for risk assessment purposes can be identified below:

- ***Dislodgeable Residue Dissipation and Reentry Interval Calculations For Crops Treated With Products Containing Phosmet:*** Submitted by Stauffer (now Zeneca) Chemical Company; Study Completion Date: 10/22/86; Report Date: 1/16/87; Authors: Dick Knarr, Yutaka Iwata, and Kay Curry; EPA MRID 404253-01.

This study was reviewed by the Agency in 1991. The review indicated that this study was considered acceptable to the Agency based on the review criteria appropriate for that era. The review can be identified by the following information:

- ***Review of Postapplication/Reentry Data Submitted to Support the Reregistration of Phosmet and Revision of Data Required by the 8/30/91 DCI for Phosmet (HED Project # 9-0839):*** A memo from Peg Perreault of the former Occupational and Residential Exposure Branch of HED to Lois Rossi, Special Review and Reregistration Division.

This document is a review of the data included in MRIDs 401223-01 and 404253-01. Release of this review memo from the Agency to the registrants prompted two additional chemical-specific submissions including:

- ***Phosmet Dermal Passive Dosimetry Exposure Addendum to MRID 404253-01:*** Submitted by the Gowan Company, Yuma Arizona; Completion Date: 12/8/92; Author: E. Codrea; EPA MRID 425958-01 (submitted with 12/14/92 letter described below).

- ***Letter from Gowan Company, Yuma Arizona to Ms. Brigid Lowery of EPA/OPP/SRRD (Phosmet CRM) Dated December 14, 1992:*** Author: Elizabeth Codrea, Regulatory Product Manager; EPA MRID 425958-00.

<u>MRID 404253-01:</u> Dislodgeable foliar residue levels were quantified from two crops (pears and Zinfandel variety grapes) that were selected to represent the crops for which phosmet is registered. Phosmet, formulated as Imidan 50-WP, was used to make all applications. All study sites were located in California. Pears, representing the remaining tree fruits and nut crops, were treated at an application rate of 5 lb ai/acre which is the current label maximum for pears. Grapes, representing the remaining crops, were treated at an application rate of 1 lb ai/acre which is the current maximum application rate for blueberries, and near the maximum application rate of 1.5 lbs ai/acre for grapes. The Iwata leaf punch/aqueous surfactant method was used to collect all samples. A 1 inch diameter punch was used in all cases and 48 punches were collected in each sample for a total double-sided surface area per sample of 480 cm^2. Based on sample surface area and the available recovery data (i.e., a low fortification level of 1µg/sample), the limit of quantification was defined as 0.002 $\mu g/cm^2$ (i.e., this applies to both phosmet and phosmet oxon residue levels that were both screened for). All field samples collected in this study were above the limit of quantification.

Pears: Imidan 50-WP was applied to a commercial, established planting of Bartlett pears located near Walnut Grove, California. Imidan 50-WP was applied once using an airblast sprayer at a rate of 4.8 lb ai/acre. Samples were collected on days 0, 1, 2, 3, 4, 5, 7, 10, 14, 21, and 28 days postapplication Weather conditions were typical, and no rainfall was reported during the study. Based on the labeling information for pears and other tree crops at the time of the study, the high application rate is 5.0 lb ai/acre, the preharvest interval is 7 days, and phosmet can be applied as needed. The dissipation data for pears are presented in Table 2 of Appendix C of "The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Phosmet" (DP262366) [*Available:* Special Docket EPA-HQ-OPP-2007-0151, at www.regulations.gov].

Field and laboratory recovery data were generated in this aspect of the study. Field recovery for phosmet was 82.5 percent (CV 9.3, n = 8) while field recovery for phosmet oxon was 93.2 percent (CV 6.9, n=10). Laboratory recovery for phosmet was 89.4 percent (CV 6.7, n = 7) while laboratory recovery for phosmet oxon was 95.1 percent (CV 5.0, n=7). The residue levels presented in Table 2 were not apparently corrected for recovery by the investigators.

Grapes: Imidan 50-WP was applied to a commercial, established planting of Zinfandel grapes located near Lodi, California. Imidan 50-WP was applied by an airblast sprayer at a rate of 0.94 lbs ai/acre. One application was made. Samples were collected on days 0, 1, 3, 4, 6, 9, 13, 20, and 27 days postapplication Weather conditions were typical during the study (i.e., no unusual events). Based on the labeling information for grapes and other crops, the high application rate is 1.5 lb ai/acre, the preharvest interval is 7 days, and phosmet can be applied as needed between egg hatch and pupation for leaffolder, leafroller, and western grape skeletonizer. The dissipation data for grapes are presented in Table 3 of Appendix C of "The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Phosmet" (DP262366) [*Available:* Special Docket EPA-HQ-OPP-2007-0151, at www.regulations.gov]. Field and laboratory recovery data were generated in this aspect of the study. Field recovery for phosmet was 96.9 percent (CV 6.4, n = 7) while field recovery for phosmet oxon was 98.0 percent (CV 5.2, n=9). Laboratory recovery for phosmet was 90.2 percent (CV 7.9, n = 5) while laboratory recovery for phosmet oxon was 93.8 percent (CV 10.6, n=5). The residue levels presented in Table 3 were not apparently corrected for recovery by the investigators.

These studies are of sufficient quality to be used for exposure and risk assessment purposes and have been used in a number of past occupational and residential exposure risk assessment documents and in the July, 2006 IRED.

1.1.4. Application of the Study Data to the Exposure Scenarios

This assessment pertains to the nine crops specified in the *Reregistration Decisions on Nine Phosmet Restricted Entry Intervals* of January, 2007. Dislodgeable foliar residue studies were submitted for only two crop groups (deciduous tree crops and vine/trellis crops). It is relevant to note for risk characterization that the DFR studies took place at California-based sites, in dry conditions. Generalizing the DFR dissipation to other locations, any ambient conditions with additional precipitation would generally mean less residue is available for transfer to the skin of field workers. Based upon the available DFR field trial information, the data were extrapolated from the DFR studies to the labeled crops.

1.1.5. Exposure Assumptions, Factors and Transfer Coefficients

The following assumptions, factors and transfer coefficients were used for calculating the occupational postapplication risk estimates:

- Short- and intermediate-term exposures were assessed for all available postapplication scenarios.

- The relevant toxicological information used for occupational postapplication short- and intermediate-term assessment (i.e., same PoD for assessing both exposure durations) are addressed above in section 1.1.1.

- The exposure durations for short- and intermediate-term and transfer coefficients reflect current Agency policy.

- Maximum application rates were used to calculate risk estimates for the postapplication scenarios.

- When the Agency extrapolated the available DFR data to other crops, the data are adjusted for differences in application rate using a simple proportional approach. This approach seems to be the most appropriate given the data available. This approach is commonly used by the Agency to conduct postapplication risk assessments.

- Risks were calculated using generic transfer coefficients that represent many different types of cultural practices. A listing of the transfer coefficients used in this assessment is given in Table 3, below. Most of these transfer coefficients were taken from the Agency's revised Policy 3.1 Science Advisory Council for Exposure Policy Regarding Agricultural Transfer Coefficients (August 7, 2000).

The transfer coefficients for highbush blueberries were taken from a study recently submitted by the ARTF (MRID 45138201) on blackberries.

- Blackberry ARTF data (ARF-020) is used as a surrogate for the blueberry transfer coefficient and the activity groups used for the other transfer coefficients are not directly comparable. This study has a primary review by Versar and a secondary review from PMRA (MacMillan, PMRA).

- Discussion around the risk estimates for both short- and intermediate-term risks are based upon the restricted entry intervals identified in *Reregistration Decisions on Nine Phosmet "Time-Limited" Uses*, January, 2007.

- The use of personal protective equipment or other types of equipment to reduce exposures for postapplication workers is not considered a viable alternative for the regulatory process except in specialized situations (e.g., a rice scout will wear rubber boots in flooded paddies). This is described in some detail in the Agency's Worker Protection Standard (40 CFR 170).

Table 3 - Postapplication Exposure Scenarios and Transfer Coefficients

Crop Type (Specific Crops)	Postapplication Exposure Scenarios	Transfer Coefficient (cm^2/hr)
Tree, Fruit, Deciduous (pears, apples, apricots, peaches, nectarines, plums, prunes,)	Very Low - propping Low - Irrigation, scouting, weeding High – Pruning, training, tying, harvesting Very High – Thinning	100 1000 1500 3000
Vine/Trellis (Grape)	Low - Hedging, irrigation, scouting, hand weeding Medium - Scouting, training, tying High – Leaf pulling, thinning, pruning, training/tying Very High – Cane Turning and Tabling Grapes	500 1000 5000 10000[1]
Vine/Trellis (Highbush Blueberries)	High Exposure	1100[2]

1 – TC for short-term exposures only; BEAD has provided HED with information that this activity pattern does not occur for the intermediate-term exposure duration
2 - *ARTF surrogate Transfer Coefficient (MRID 451382-01)*

1.1.6. Occupational Postapplication Exposure and Risk Estimates

Phosmet Risk Summary:

The post application risks for phosmet are summarized in Table 4 and details are presented in Appendix A. Both the short- and intermediate term postapplication risk estimates are based on a toxicological PoD (oral BMD_{10} – 1 mg/kg/day) selected from a subchronic neurotoxicity study in rats (MRID 44811801) and considered co-critical with the 21-day MPI study (MRID 44795801). The LOC for short- and intermediate-term postapplication exposures is an MOE of 100. Within each crop group, differing transfer coefficients were used to represent different types of cultural practices which were applicable to each crop group. Most of the risk estimates for "very high" exposure activities (i.e., thinning) and one of the "high exposure" activities (i.e., harvesting) for phosmet exceed HED's level of concern (i.e., MOEs are less than 100) at the REIs specified in the Agency decision document, *Reregistration Decisions on Nine Phosmet "Time Limited" Uses*, dated January 18, 2007. The time needed to achieve MOEs of 100 for short-term risks for the "very high" exposure category ranges from 7 to 24 days, with the longest time needed for cane turning and girdling grapes (Applicable on to grapes grown East of the Rocky Mountains).

While the PoD is the same for short- and intermediate-term postapplication risk assessment, there are some activity-based differences in the potential exposure patterns that are of interest. According to information provided by BEAD, cane turning and girdling of grapes is an exposure activity that occurs for the short-term exposure duration, but not the intermediate-term exposure duration. Therefore, the time needed to achieve MOEs of 100 for intermediate-term term risks for the "very high" exposure category ranges from 7 to 17 days, with the longest time needed for thinning deciduous tree fruits.

Table 4 - Phosmet Postapplication Short- & Intermediate-Term Risks
(Reflecting Label Maximum Application Rates)

Crop Group	**Application Rate (lb a.i/acre)**	MOE; (days till MOE>100)			
		Very Low	**Low**	**High** (Harvesting)	**Very High** (Thinning)
		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Pears/Apples (West of Rockies)*	4	1550	160	100	**52** (17)
		MOE on REI [Day 4]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Apples (East of Rockies)*	4	1270	130	**85** (7)[1]	**42 (17)**
		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Peaches, nectarines (West of the Rockies)*	3	2070	210	140 [2]	N/A[3]
		MOE on REI [Day 4]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Peaches, nectarines (East of the Rockies)*	3	1700	170	110 [4]	**57** (13)

		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Plums, prunes (West of the Rockies)*	3	2070	210	140 [5]	N/A[6]
		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Plums, prunes (East of the Rockies)*	3	2070	210	140 [7]	**69** (13)
		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Apricots (West of the Rockies)*	3	2070	207	140 [8]	N/A [9]
		MOE on REI [Day 7]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *Apricots (East of the Rockies)*	3	2070	210	140 [10]	**69** (13)
		MOE on REI [Day 4]* (Days when MOE > 100)			
Tree, Fruit, Deciduous *North east Apples (tank mix with methomyl [lannate], only)*	2	2550	260	170[11]	**85** (7)
		MOE on REI [Day 14]* (Days when MOE > 100)			
Vine/trellis *Grapes (West of the Rockies)*	1.5	N/A	520[12]	N/A[13]	N/A[13]
		MOE on REI [Day 14]* (Days when MOE > 100)			
Vine/trellis *Grapes (East of the Rockies)*	1.5	N/A	520[12]	100	**51**(24)[14]
		MOE on REI [Day 1]* (Days when MOE > 100)			
Vine/trellis *Blueberries*	1	N/A	N/A[15]	225[16]	N/A

+ Bolded MOEs exceed HED's level of concern (i.e., MOEs<100)

***** - Reregistration Decisions on Nine Phosmet "Time-Limited" Uses, January 18, 2007

1 - The PHI for apples is 7 days, so no hand harvesting would take place at 4 days. The MOE at 7 days is 100.

2- The PHI for peaches is 14 days, so no hand harvesting would take place at 7 days. The MOE at 14 days is 220.

3 - In the January 18, 2007 decision document for phosmet, thinning is prohibited as a postapplication exposure activity after phosmet applications to peaches West of the Rockies.

4 - The PHI for peaches is 14 days, so no hand harvesting would take place at 7 days. The MOE at 14 days is 220.

5 - In the January 18, 2007 decision document for phosmet, hand harvesting of plums and prunes is prohibited for 14 days after application, so no hand harvesting would take place at 7 days. The MOE at 14 days is 220.

6 - In the January 18, 2007 decision document for phosmet, thinning is prohibited as a postapplication exposure activity after phosmet applications to plums and prunes West of the Rocky Mountains.

7 - In the January 18, 2007 decision document for phosmet, hand harvesting of plums and prunes is prohibited for 14 days after application,
8 - The PHI for apricots is 14 days, so no hand harvesting would take place at 7 days. The MOE at 14 days is 220.
9 – In the January 18, 2007 decision document for phosmet, thinning is prohibited as a postapplication exposure activity after phosmet applications to apricots West of the Rockies.
10 – The PHI for apricots is 14 days, so no hand harvesting would take place at 7 days. The MOE at 14 days is 220.
11 – The PHI for northeast apples (tank mix with methomyl, only) is 8 days, so no hand harvesting would take place at 4 days. The MOE at 8 days is 220.
12 – The MOE of 520 relates to medium exposure activities for grapes. (See Table 3 for additional information).
13 – In the January 18, 2007 decision document for phosmet, all hand labor activities EXCEPT for scouting, hand weeding, and irrigating, are prohibited after phosmet application to grapes West of the Rockies.
14 – According to information provided by BEAD, cane turning and girdling of grapes occurs only as a short-term exposure activity, not an intermediate-term exposure activity
15 – ARTF ARF-020 data used for surrogate TC; HED expects other blueberry postapplication work to result in lower exposures than the "high" exposure activity shown.
16 – The PHI for blueberries is 3 days, so no hand harvesting would take place on the first day after application. The MOE at 3 days is 260.

Risk estimates for workers tending blueberries are represented for both short- and intermediate-term exposure durations use data extrapolated from the Agricultural Rentry Task Force's ARF-020 [MRID 451382-01]. The ARTF transfer coefficient (TC) studies do not present TC data that are directly comparable to the HED's default TC values on a exposure category basis. The TC value used to estimate phosmet risk most closely approximates the "high" exposure potential used in the default TC studies, and are presented in that category in the risk estimate summary table. Reentry workers conducting activities with a lower exposure potential (e.g., scouting and irrigation) than harvesting and pruning would have a lower exposure estimate than risk estimates presented in this document (ST/IT MOE @ Day 0: 210). The risks for reentry workers for irrigation and scouting using the default TC value of 500 would be roughly 2x lower (i.e., a 2x higher MOE) than the risk estimates presented for workers harvesting highbush blueberries in this document.

1.1.7. Summary of Occupational Postapplication Risk Concerns and Data Gaps

A summary of all the occupational postapplication risks of concern for phosmet is included in Table 5, below.

The risk estimates exceed HED's level of concern (i.e., MOEs are below the LOC of 100) in all the "very high" activity grouping. Typical activities for the "very high" activity grouping includes thinning fruit trees.

The risk estimates exceed HED's level of concern (i.e., MOEs are below the LOC of 100) for one postapplication activity scenario in the "high" activity grouping for both exposure durations. That activity pattern represents workers harvesting deciduous tree fruits (specifically apples east of the Rocky Mountains).

For the remainder of the postapplication exposure scenarios, the risk estimates do not exceed HED's level of concern (i.e., MOEs are above the LOC of 100) for all postapplication worker activity patterns in the "very low", "low" and "medium" exposure activity groupings. Typical activities in those activity groupings include propping, irrigation, and scouting.

Table 5 - Summary of Phosmet Postapplication Risks of Concern per Crop and Activity Groups

Crop Group	Exposure Duration	Exposure Activity Grouping – Risk of Concern Identified?				
		Very Low	Low	Medium	High	Very High
Deciduous Fruit Trees (Pears)	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (Apples – west of Rockies)	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (Apples – east of Rockies)	ST/IT	No	No	N/A	**Yes**	**Yes**
Deciduous Fruit Trees (Apples – northeast) [for tank mix]	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (Peaches, nectarines – west of Rockies)	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (Peaches,	ST/IT	No	No	N/A	No	**Yes**

Table 5 - Summary of Phosmet Postapplication Risks of Concern per Crop and Activity Groups						
Crop Group	**Exposure Duration**	**Exposure Activity Grouping – Risk of Concern Identified?**				
		Very Low	**Low**	**Medium**	**High**	**Very High**
nectarines – east of Rockies)						
Deciduous Fruit Trees (Apricots – west & east of Rockies)	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (plums/prunes – west of Rockies)	ST/IT	No	No	N/A	No	**Yes**
Deciduous Fruit Trees (plums/prunes - east of Rockies)	ST/IT	No	No	N/A	No	**Yes**
Vine/trellis (blueberries)	ST/IT	N/A	N/A	N/A	No	N/A
Vine/trellis[A] (grapes)	ST	No	No	No	No	**Yes**
	IT	N/A	N/A	No	No	N/A
Representative Exposure Activities per Activity Grouping		**Propping**	**Irrigation, Scouting**	**Grape Scouting, training grapes[B]**	**Harvesting**	**Thinning, cane turning/girdling [grapes only][C]**

A – Vine/trellis risk summary has been broken into two line items to reflect the difference in activity patterns based on exposure duration.
B - The "medium" exposure activity grouping is relevant to scouting and training of grapes only.
C – Cane turn/girdling is an activity relevant to grapes only [short-term exposure duration only].

1.1.8. Occupational Postapplication Risk Characterization

The Agency has completed a risk assessment for both short- and intermediate-term exposures; the PoD is the same for both cases. The intermediate-term exposure assessment represents an exposure duration of greater than 30 days (i.e., intermediate-term exposures between 30 days and 6 months). It should be noted that even though the Agency has completed this assessment, it is unlikely that many individuals will be exposed in this manner given the way that phosmet is likely used and based on the recent use and usage data provided that indicate (in agriculture) that phosmet is generally used up to about a maximum of 5 times per year. Even with a relative few number of applications per growing season, postapplication exposure activities like harvesting and thinning can take place over a course of several weeks. HED does not expect postapplication workers to be exposed to maximum residues every day over the course of the short-term exposure duration (up to 30 days). For the intermediate-term exposure duration, risk estimates are likely a conservative estimate of risk (i.e., intermediate-term risk calculations likely overestimate exposure and risk).

The chemical-specific exposure and dislodgeable foliar residue studies submitted by the registrant were reviewed by the Agency and determined to be acceptable for risk assessment purposes. The surrogate transfer coefficients used to calculate occupational postapplication exposures are based on published empirical data and are generally considered to represent reasonable estimates of dermal exposure. These transfer coefficient values are based on the use of normal long sleeved work clothing.

2. Environmental Justice and Human Studies

Environmental Justice:

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED risk assessments typically estimate risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. This document deals exclusively with occupational postapplication risk estimates for the nine crops specified in the *Reregistration Decisions on Nine Phosmet "Time Limited" Uses*, dated January 18, 2007. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

Human Studies:

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies (listed in Appendix B), which comprise the Pesticide Handlers Exposure Database (PHED), have been determined to require a review of their ethical conduct, and have received that review.

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